K052875

DEC 2 7 2005

Exhibit #1

510(k) Summary

Submitter's name: Dan Woody
Summit Manufacturing, L.L.C.
1307 N. Glenville Dr.
Richardson, TX 75081
Phone: 972-235-9212
FAX: 972-235-0421
E-mail Address: Dan.Woody@namedical.com

Contact person: Dan Woody

Date prepared: October 4, 2005

Device Name: ProStim Reusable Neurostimulation Electrodes

Classification Name: Neurostimulation Electrodes

Predicate devices: K050469 (Naimco, Inc.)
K010431 (Lead-Lok, Inc.)

Device Description: ProStim Reusable Neurostimulation electrodes are non-sterile, disposable laminated, flexible structures composed of materials commonly used in this application:

First Layer—White spun laced nonwoven tape or White 1/32" thick Polyethylene foam or a polypropylene substrate, coated with biocompatible adhesive.

Second Layer— Conductive plastic film.

Third Layer—Biocompatible conductive hydrogel coupling media (

The electrodes are designed for single-patient/multiple application use. Because of the adhesive nature of the biocompatible hydrogel, no securing materials are required to secure the device to the patient's skin. The electrode has one type of connection point that can be used to connect the stimulation device to the electrodes. This connection point is compatible with all standard, marketed Neurostimulation devices.

Lead wire assembly – 6" wire with .080 in. diameter female socket connected to one side of the wire.

Predicate Technological Characteristics Comparison: ProStim Reusable Neurostimulation electrodes are technologically equivalent to the predicate devices. They are physically and technically similar to those currently being marketed for "Neurostimulation" i.e., TENS (Transcutaneous Electrical Nerve Stimulation), MENS (Microcurrent Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) and PGS (Pulsed Galvanic Stimulation).

Safety and Effectiveness: ProStim Reusable Neurostimulation electrodes are as safe and effective as the Naimco E-Z stik electrodes (K050469) and Lead-Lok (K010431) which were previously found to be substantially equivalent via 510(k) Premarket Notifications.

The first safety issue considered was whether the gel, which is used to adhere the electrode to the skin and which is the only portion of the electrode to maintain skin contact, would cause any skin irritation. **The Katecho KM 10 Series of gels (file number K00870) and the Amgel 700 Series gels (file number K983741)**, which may be used in this family of electrodes, have passed the required skin sensitivity testing criteria as specified in the Tripartite Biocompatibility Guidance for Medical Devices and ISO 10993-1 requirements for skin contact. These tests include Cytotoxicity, Sensitization, and Primary Skin Irritation Tests.

Because there are no published performance standards for Neurostimulation electrodes, Summit Manufacturing, L.L.C. uses impedance levels as the criteria for effectiveness testing. Results of the impedance testing revealed that the subject device's impedance values were comparable to the other predicate device(s) impedance values.

Based on the aforementioned information, ProStim considers its Reusable TENS/NMES electrodes to be as safe and effective as the predicate devices, as well as multiple other TENS/NMES electrodes currently being marketed including those manufactured by: Uni-Patch(k962910), MSB Limited (K980229), Axelgaard (K983741), Selective Med components, Inc. (k946230),Medtronic, Inc. (K875284), Medical Design & Manufacturing Corp. (K895604), and Labeltape Meditect, Inc. (K900656,K902719 and K894043).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2005

Summit Manufacturing, L.L.C.
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K052875
Trade/Device Name: ProStim Reusable Neurostimulation Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Codes: GXY
Dated: October 11, 2005
Received: October 12, 2005

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Exhibit B

510(k) Number (if known): K052875

Device Name: ProStim Reusable Neurostimulation Electrodes

Indications For Use:

The ProStim Reusable Neurostimulation Electrodes are intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. ProStim Reusable Neurostimulation Electrodes are designed and intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation), MENS (Microcurrent Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation).

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-The Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052875